

REMARKS

The following remarks are responsive to the Office Action dated January 30, 2003. Claims 1-9 have been deemed allowable by the Examiner. Applicants amend claims 10 and 12, and add new claims 21 through 41. Applicants submit that no new matter has been introduced by amendments to claims 10 and 12 or new claims 21-41. Claims 1-41 are now pending in this application.

35 U.S.C. § 102(B) REJECTION OF CLAIMS 10,12,13,15-17,19, 20

The Examiner rejected independent claims 10 and 12, and dependent claims 13,15-17,19, and 20 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,961,451 to Reber et al. ("Reber"). (OA, ¶2). Applicants respectfully traverse this rejection and submit that claims 10, 12, 13,15-17,19, and 20, as amended, are patentable over Reber.

CLAIM 10 IS PATENTABLE OVER REBER

In the Office Action, the Examiner cites to various sections of Reber as allegedly showing all of the aspects of claim 10. Applicants respectfully submit, however, that Reber does not disclose, teach or suggest at least "obtaining a body fluid from a tissue punctured with a lancet, the lancet being driven by a driving mechanism," as recited in Claim 10. Reber is directed to a noninvasive apparatus for noninvasively extracting a sample from a hand of an end user. (Abstract) Thus, Applicants submit that claim 10 is patentable over Reber.

CLAIM 12 IS PATENTABLE OVER REBER

Applicants respectfully submit that Reber does not teach or disclose "communication with an information management system, wherein the information management system is a centralized means for collecting and processing information for functions," as recited in claim 12. Instead, Reber discloses "an interface 36 for interfacing with an external device" and "data can be communicated between the

processor 26 and the external device.” (Col 4, lines 31-41) Reber further discloses the idea that “by uploading test information from the apparatus to an external device, the external device can process, communicate, and/or archive the information.” (Col. 9, lines 32-34) Therefore, claim 12 is allowable over Reber.

DEPENDENT CLAIMS 11, 13, AND 15-20 ARE PATENTABLE OVER REBER

Claims 13, 15-17, 19, and 20 each depend from independent claim 12, and are thus allowable for at least the reasons set forth in connection with claim 12 from which they depend.

Claims 11 and 18 were objected to as being dependent upon a rejected base claim, and each depend from independent claims 10 and 12, and are thus allowable for at least the reasons set forth in connection with claims 10 and 12 from which they depend.

35 U.S.C. §103 REJECTION OVER REBER IN VIEW OF CAUSEY

Regarding the rejection of claim 14 under 35 U.S.C. § 103(a) as allegedly unpatentable over Reber in view of US. Publication No. US2002/0002326 A1 to Causey, II et al. (“Causey”) (OA, ¶4). As discussed above, Applicants respectively submit that amended claim 12 is patentable over Reber, for at least the reasons stated above. Causey likewise does not teach or disclose “communicating with an information management system, wherein the information management system is a centralized means for collecting and processing information for functions,” as is recited in claim 12. Causey discloses a medical device module for use in a system, where a communication module is adapted to display historical data locally. Thus, Causey does not cure the deficiencies of Reber. Accordingly, claim 14, which depends from amended claim 12 should be in condition for allowance.

ALLOWABLE SUBJECT MATTER

The Examiner allowed claims 1-9. Claims 11 and 18 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. New claims 21 and 22 incorporate dependent claims 11 and 18 into their independent base claim and are therefore allowable over the prior art of record.

NEW CLAIMS

Claims 23-41 are added to more clearly define the scope of the present invention. No new matter has been added. As a nonlimiting example, support can be found with reference to Figure 2.

Independent claim 23 is allowable as it recites obtaining a body fluid from a tissue puncture created by a lancet, wherein the lancet is driven outward from a cartridge by a lancet driver and wherein the body fluid from the tissue puncture flows into the cartridge. The body fluid is housed within a cartridge having an assay sensor. Information regarding the body fluid in the cartridge is obtained from an analytical detector in communication with the assay sensor. The information is transferred to a remote location via a communication module. This combination is not shown or suggested by the cited art. Accordingly, claim 23 and its dependent claims are in condition for allowance.

Independent claim 32 is also allowable as it recites a portable medical analyzer comprising a lancet within a cartridge and a lancet driver for advancing the lancet to puncture tissue. The analyzer includes a sample pathway for receiving at least one body fluid from a tissue puncture formed by the lancet, wherein the pathway is contained within the cartridge. At least one assay sensor is housed in the cartridge wherein the sensor is adapted for at least one assay for the body fluid received by the

sample pathway. An analytical detector is provided that comprises at least one signal processor and circuitry for processing of signals from at least one detector corresponding to the assay sensor, wherein the detector adapted to detect information from the assay. The device includes a communication module coupled to the signal processor, the communication module comprising a transmitter and receiver in communication with an information management system. This combination is not shown or suggested by the cited art. Accordingly, claim 32 and its dependent claims are in condition for allowance.

CONCLUSION

In view of the foregoing remarks, Applicants submit that claims 1-41 are neither anticipated nor rendered obvious in view of the prior art of record. Applicants therefore request the Examiner's reconsideration and reexamination of the application, and the timely allowance of claims 1-41.

If the Examiner believes a telephone interview would expedite the prosecution of this application, the Examiner is invited to contact Karna J. Nisewaner at (650) 849-6643.

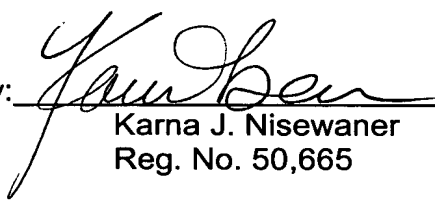
Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 50-1078.

Respectfully submitted,

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By: _____


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Appendix

10. (Amended) A method for portable medical analysis comprising:
obtaining a body fluid from a tissue punctured with a lancet, the lancet driven
by a driving mechanism;

housing said body fluid within a cartridge comprising an assay sensor module;
positioning said cartridge into an analytical detector module;
obtaining information from said analytical detector module;
displaying said information locally on a display within said communication
module; and

transferring said information to a remote location via a communication module.

12. (Amended) A portable medical analyzer comprising:
a sampling module comprising a sample port for receiving at least one body
fluid, said sampling module housed in a cartridge;

an assay sensor module housed in said cartridge, said assay sensor module
comprising at least one assay sensor adapted to at least one assay for said body
fluid;

an analytical detector module comprising at least one signal processor and
circuitry for processing of signals from at least one detector corresponding to said
assay sensor, said detector adapted to detect information from said assay;

a communication module coupled to said signal processor, said
communication module comprising a transmitter and receiver in communication with
an information management system, wherein the information management system is
a centralized means for collecting and processing information for functions.

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21. (NEW) A method for portable medical analysis comprising:
obtaining a body fluid;
housing said body fluid within a cartridge comprising an assay sensor module;
positioning said cartridge into an analytical detector module, wherein
positioning said cartridge comprises breaking a pressure seal on said cartridge, said
breaking adapted to transfer said body fluid to at least one assay sensor in said
assay sensor module;
obtaining information from said analytical detector module;
displaying said information locally on a display within said communication
module; and
transferring said information to a remote location via a communication module.

22. (NEW) A portable medical analyzer comprising:
a sampling module comprising a sample port for receiving at least one body
fluid, said sampling module housed in a cartridge;
an assay sensor module housed in said cartridge, said assay sensor module
comprising at least one assay sensor adapted to at least one assay for said body
fluid;
an analytical detector module comprising at least one signal processor and
circuitry for processing of signals from at least one detector corresponding to said
assay sensor, said detector adapted to detect information from said assay; and
a communication module coupled to said signal processor, said
communication module comprising a transmitter and receiver in communication with
an information management system, wherein said information management system
comprises a means for brokering medical data.

23. (NEW) A method for portable medical analysis comprising:
obtaining a body fluid from a tissue puncture created by a lancet, wherein the lancet is driven outward from a cartridge by a lancet driver and wherein the body fluid from the tissue puncture flows into the cartridge;
housing said body fluid within the cartridge, said cartridge having an assay sensor;
obtaining information regarding said body fluid in the cartridge from an analytical detector in communication with the assay sensor; and
transferring said information to a remote location via a communication module.

24. (NEW) A method as in claim 23 further comprising displaying said information locally on a display coupled to said communication module.

25. (NEW) A method as in claim 23 wherein said communication module is adapted to transfer said information to a remote location.

26. (NEW) A method as in claim 23 wherein said cartridge includes a plurality of assay sensors, each of said sensors performing the same analysis on the body fluid.

27. (NEW) A method as in claim 23 wherein said cartridge includes a plurality of assay sensors, each of said sensors performing a variety of different analysis on the body fluid.

28. (NEW) A method as in claim 27 wherein at least one of said sensors provides analysis for one of the following: a blood chemistry, hematology, immuno-

diagnostics those for drugs of abuse, serum cholesterol, glucose, FOBT, pregnancy, ovulation, DNA based assays, immuno assays, proteomics and genomics.

29. (NEW) A method as in claim 23 wherein said transmitter uses at least one interface chosen from radio frequency, infrared and standard ports.

30. (NEW) A method as in claim 23 wherein said lancet is driven by an electromechanical lancet driver.

31. (NEW) A method as in claim 23 wherein said lancet is driven by an electrical lancet driver.

32. (NEW) A portable medical analyzer comprising:

- a lancet within a cartridge;
- a lancet driver for advancing said lancet to puncture tissue;
- a sample pathway for receiving at least one body fluid from a tissue puncture formed by said lancet, said pathway contained within the cartridge;
- at least one assay sensor housed in said cartridge, said sensor adapted for at least one assay for said body fluid received by said sample pathway;
- an analytical detector comprising at least one signal processor and circuitry for processing of signals from at least one detector corresponding to said assay sensor, said detector adapted to detect information from said assay; and
- a communication module coupled to said signal processor, said communication module comprising a transmitter and receiver in communication with an information management system.

33. (NEW) A portable medical analyzer according to claim 32, wherein:

said communication module comprises a transmitter adapted to transfer said information to a remote location.

34. (NEW) A portable medical analyzer according to claim 32, wherein:
said communication module comprises a receiver adapted to communicate with a remote location.

35. (NEW) A portable medical analyzer according to claim 32, wherein:
communication module has a transmitter using one of the following for transmission of information to a remote location: infrared or radio frequency signals.

36. (NEW) A portable medical analyzer according to claim 32, wherein:
communication module includes at least one of the following: a processor, display, RF chip, antenna, an operating system, RAM, DRAM, or a PCMCIA interface.

37. (NEW) A portable medical analyzer according to claim 32, wherein:
said communication module is adapted to couple with said analytical detector via said standard port.

38. (NEW) A portable medical analyzer according to claim 32, wherein:
said transmitter is adapted to include at least one interface chosen from radio frequency, infrared and standard ports.

39. (NEW) A portable medical analyzer according to claim 32, further comprising:

an information storage unit for storing said information locally on said portable medical analyzer.

40. (NEW) A portable medical analyzer according to claim 32, wherein said driver comprises an electromechanical lancet driver.

41. (NEW) A portable medical analyzer according to claim 32 wherein said driver comprises an electrical lancet driver.